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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/037,460	03/10/98	HASTINGS	G 325800-626 (P)

022195
HUMAN GENOME SCIENCES INC
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ROCKVILLE MD 20850

HM12/0318

EXAMINER

SAOUD, C

ART UNIT

PAPER NUMBER

1646

6

DATE MAILED:

03/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/037,460

Applicant(s)

Hastings et al.

Examiner

SAOUD

Group Art Unit

1646

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P r i d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 21-52 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 21-52 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Applicant's preliminary amendment of 10 March 1998, paper #2, has been received and entered. The amendment canceled claims 1-20 and added new claims. Applicant should note that although the amendment stated that claims 21-53 were added, there was a typographical error in the numbering of the claims (claim 46 was missing), so claims 47-53 were renumbered according to Rule 121. Claims 21-52 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 21-34 and 47, drawn to polypeptides of SEQ ID NO:2, classified in class 530, subclass 399, for example.
 - II. Claims 35-36, drawn to compounds of an undisclosed constitution which activate the polypeptide of SEQ ID NO:2, classified in class undeterminable, subclass undeterminable.
 - III. Claims 37-38, drawn to compounds of an undisclosed constitution which inhibit activation of the polypeptide of SEQ ID NO:2, classified in class undeterminable, subclass undeterminable.
 - IV. Claims 39-40, drawn to method of treatment by administration of the compound of Group II, classified in class undeterminable, subclass undeterminable.
 - V. Claims 41-42, drawn to method of treatment by administration of DNA, classified in class 514, subclass 44, for example.
 - VI. Claims 43-46, drawn to methods of diagnosing a disease by determining a mutation in DNA, classified in class 536, subclass 24.3, for example.

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VII. Claims 48 and 50-52, drawn to diagnostic methods of measuring the polypeptide, classified in class 436, subclass 501, for example.

VIII. Claim 49, drawn to methods of identifying a compound that interacts with the polypeptide of SEQ ID NO:2, classified in class 435, subclass 4, for example.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and (II-III) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to independent and distinct compounds which have different modes of operation, different functions and different effects. Specifically, the compounds of Groups II and III have opposing effects, and each acts differently on the polypeptide of Group I.

5. Inventions I and (IV-VI and VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to the polypeptide (Group I) and various methods (IV-VI, VIII), wherein none of the methods rely on the polypeptide of Group I for their practice.

6. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I is related in that the method of

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Group VII measures the presence of the polypeptide, however, the polypeptide could be used in an entirely different method, such as in a therapeutic method or a method of generating antibodies.

7. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group II could be used in an entirely different process, such as a method of generating antibodies, rather than in the method of Group IV.

8. Inventions II and (V-VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the methods of Groups V-VIII do not require the compound of Group II.

9. Inventions III and (IV-VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the methods of Groups IV-VIII do not require the compound of Group III.

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10. Inventions IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct methods which have different starting materials, different method steps, and different goals.

11. The inventions of each named pair can be shown to be distinct because they do not rely upon each other for their ultimate use and they require non-coextensive literature searches. The compounds are structurally different and the methods have different goals, method steps, and/or starting materials. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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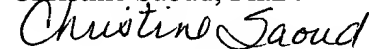
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 16, 1999

Christine Saoud, Ph.D.



Patent Examiner

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RESTRICTION ELECTION FACSIMILE TRANSMISSION

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